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Running shoes for preventing lower limb running injuries in adults (Protocol)

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TABLE OF CONTENTS

[Intervention Protocol]

Running shoes for preventing lower limb running injuries in adults

Nicola Relph[1], Henrike Greaves[2], Ross Armstrong[3], Phillip Gichuru[1], Trevor D Prior[4], Ian B Griffiths[5], Sally Spencer[6], Paola Dey[1], Ben Langley[3]

[1]Faculty of Health and Social Care, Edge Hill University, Ormskirk, UK. [2]Liverpool John Moores University, Liverpool, UK. [3]Department of Sport & Physical Activity, Edge Hill University, Ormskirk, UK. [4]Podiatric Surgery, Homerton University Hospital, London, UK. [5]Pure Sports Medicine, London, UK. [6]Postgraduate Medical Institute, Edge Hill University, Ormskirk, UK

Contact address: Nicola Relph, Faculty of Health and Social Care, Edge Hill University, Ormskirk, UK. Nicola.Relph@edgehill.ac.uk.

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess the effects (benefits and harms) of running shoes for preventing lower-limb running injuries in adult runners.

BACKGROUND

Description of the condition

Running is amongst the top three most popular adult sport and leisure physical activities globally (Hulteen 2017). It has various health benefits: for example, runners have a 30% lower risk of all-cause mortality and a 45% lower risk of cardiovascular mortality compared with non-runners (Lee 2014). However, running can also result in musculoskeletal and soft tissue injuries.

It has been estimated between 19.4% and 79% of runners sustain an injury, of which the great majority (around 97%) are in the lower limb and are evenly distributed across the knee, lower leg, and foot and ankle (Lun 2004; Malisoux 2015; Taunton 2002; Tonoli 2010; Van Gent 2007; Van Middelkoop 2008). Running injury incidence rates of 17.8% for novice runners, 7.7% for recreational runners and 3.5% for elite or professional runners per 1000 hours of running have been reported (Begizew 2018; Vidbæk 2015). Furthermore, between 10 to 35 injuries per 100 recruits per month occur in military populations (Kaufman 2000).

A general definition of injury is a significant complaint perceived and defined by the athlete (Parkkari 2004). Common running injuries include muscular-tendon strains, ligament sprains, tendinopathies, specific knee injuries (patello-femoral pain, chondromalacia patella and meniscal damage), stress fractures, medial tibial stress syndrome (or 'shin splints'), plantar fasciitis (pain in the underside of the foot) and iliotibial band syndrome (pain in the tissue between the hip and the knee) (Bird 1997; Lopes 2012; Lemont 2003; Reinking 2012). Severity of injury has been considered in terms of: 1) social and health impacts, for example, work days lost (Van Mechelen 1997), loss of employment or military career (Hespanhol 2015; Kaufman 2000); and loss of health impacts due to long-term reduction in physical activity (Van der Worp 2015); 2) impacts on running, for example, level of abil-

ity to continue to run (Marti 1988), or lost running days (Van Mechelen 1997); and 3) clinical impacts such as grading systems for strains and sprains (Lynch 1999; Mueller-Wohlfahrt 2013).
The cause of running injuries is complex and multifactorial (Bertelsen 2017). However, the process that immediately precedes injury concerns the involved structure's capacity being exceeded (Bertelsen 2017; Hulme 2017). Overuse injuries, such as stress fractures and patello-femoral pain, accumulate over time and arise from micro-traumas that create damage (Ferber 2009; Saragiotto 2014). Acute trauma injuries occur after a sudden event such as forceful ankle movement leading to an ankle sprain (Van Mechelen 1997).

Description of the intervention

There are many different types of running shoes available. These generally incorporate design features that may reduce the risk of lower limb injuries (Davis 2014). Recently Ramsey 2019 has categorised these characteristics into nomenclature, measurements, qualitative features and subjective features.
Most studies have used the running shoe types listed in the nomenclature category. They include neutral and cushioned shoes (typically used interchangeably in practice) designed to reduce the load when striking the ground (Davis 2014; Langley 2015); motion control shoes, designed to reduce the amount or rate, or both, of rearfoot and midfoot motion during ground contact (Davis 2014; Langley 2015); stability shoes designed to offer some motion control and cushioning (Davis 2014; Langley 2015); and minimalist running shoes that aim to mimic barefoot running and are designed with high levels of flexibility and lack of motion control or stability features (Esculier 2015). However, the combination of features included in a particular type of running shoe often vary both within and between brands and may overlap. Although other, less common types of nomenclature are reported in Ramsey 2019, the typical design features of the most commonly reported shoes are detailed in Table 1.
The measurements category lists objective detail on the structure of the shoe (e.g. heel-toe drop); the qualitative features category provides visual inspection details (e.g. outer-sole wear patterns), and the subjective features include comfort and cost (Ramsey 2019). However, these are not characteristics unique to running shoes. Shoe prescription based on assessment of lower limb alignment is also included in the subjective features category (Ramsey 2019). Furthermore, running shoes have been recommended to runners based upon a scale of foot type measurements known as foot posture (Napier 2018). In general, runners tend to be prescribed shoes that have some aspect of elevated cushioned heels and subtalar motion control features (Richards 2009). However, more specifically, motion control shoes may be recommended for runners with an excessively pronated foot (the foot tends to roll inwards), stability shoes for those with a pronated to neutral foot posture and cushioned or neutral running shoes for neutral to supinated (the foot tends to roll outwards) foot posture (Table 1 Davis 2014).

How the intervention might work

Running shoes are designed to prevent overuse injuries; it is unclear if acute injuries are also prevented. Shoes can be designed with motion control and cushioning features (Davis 2014; Reinschmidt 2000). Motion control features aim to reduce excessive foot motion and hence increase the efficiency of the foot during the push-off phase and cushioning features modify rear foot motion and impact forces and can reduce the amount or rate of force applied to the body (Butler 2007; Clarke 1983; Davis 2014; Dinato 2015; Milani 1997; Perry 1995; Reinschmidt 2000; TenBroek 2014). There may be differences in (rear) foot and knee movement (Cheung 2007; Hutchison 2015; Langley 2018; Langley 2019; Lilley 2013; Rose 2011), changes in foot striking patterns (which part of the foot makes contact with the ground) and modification of impact forces when wearing different types of running shoes (Sinclair 2013; Squadrone 2009). Because each running shoe design may modify different lower limb movements, it is possible that specific injuries may be reduced for each of these footwear designs. For example, the inclusion of an elevated heel in running shoes may reduce Achilles tendon strains and thus Achilles tendon injury (Rabusin 2019). Subtalar motion control characteristics are thought to reduce injuries that occur medially, including tibial stress syndrome and patello-femoral pain (McKenzie 1985; Messier 1988). There has also been some limited evidence that older running shoes may be less likely to reduce injuries due to the deterioration of design features (Gardner 1988). Modifications attributed to running shoes may reduce injury risk; however, injury rates are not typically reported.
Footwear design has been based upon theory of how the foot should function (Root 1971; Root 1977). Root suggested that the foot has an optimum position about which it should move and deviations away from this would increase injury risk (Root 1971; Root 1977). This concept gave rise to a wide range of running shoe adaptations which aimed to control foot function, primarily by reducing foot motion. Kirby proposed an alternative concept, which detailed how the external forces acting upon a foot would influence the loading of the structures within the foot and may explain how shoes provide a means of modifying injury risk without movement adaptations (Kirby 1987; Kirby 1989; Kirby 1992). More recently, two alternative injury theories have been proposed: the muscle tuning paradigm and the preferred movement pathway theory (Nigg 2015; Nigg 2017). The muscle tuning paradigm suggests that muscles vibrate as a result of impact and the muscular activation required to stop this increases the rate of fatigue and then injury risk. The preferred movement pathway theory suggests that runners have their own preferred movement pathway and that footwear may reduce muscle activation levels by working with rather than against this natural pattern of movement.

Why it is important to do this review

Running injuries have a societal and individual economic impact through loss of productivity and associated costs of health care (Hespanhol 2015), and can lead to a reduction in physical activity entirely (Buist 2010; Van der Worp 2015). As there is a clear link between regular physical activity and increased health and well-being, running-related injury prevention is an important public health issue. Running injuries can also have negative consequences for professional populations such as for military recruits due to a decrease in military readiness (Bullock 2010). Runners attribute injury to their footwear (Rothschild 2012; Saragiotto 2014), and specific features of a running shoe are claimed to reduce the risk of injury (Nigg 2017). This has partly driven the now multi-billion dollar sports footwear industry. However, due to the continuous evolution of injury risk theories surrounding foot position, footwear design and injury risk, the evidence to support running shoes as an injury prevention method must also be continuously evaluated; albeit that, inevitably, evidence about running shoe prescription will lag behind the adoption of theory (Richards 2009). A previous Cochrane Review on all interventions to prevent running injury concluded that, "there is no evidence that the prescription of running shoes based on assessment of foot shape, when compared with standard running shoes, offers additional protection in military recruits" (Yeung 2011). Furthermore, Leppänen 2014 reported that basketball boots, rugby footwear and infantry boots did not reduce lower-limb injury in professional sports people and military recruits but did not consider running shoes. Therefore, there is a need for decisions and advice on running footwear to be based on high-quality evidence of the effectiveness of specific running shoes for injury prevention in all types of runners. This review will focus specifically on running shoes in a broad population of adult runners. The aim of this review is to evaluate and update the current evidence on the effectiveness of running shoes for preventing lower limb running injuries in adult runners.

OBJECTIVES

To assess the effects (benefits and harms) of running shoes for preventing lower-limb running injuries in adult runners.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs) and quasi-RCTs. We expect most studies will be individually randomised but will also include cluster-RCTs. We will also include cross-over studies but only use data from the first, pre-cross-over phase, to eliminate potentially irreversible carry-over effects (e.g. injury). We will include studies reported irrespective of their publication status: full text, abstract only and non-published data.

Types of participants

We will include novice, recreational and professional or elite, including service personnel (e.g. military who run as part of their training), adult runners. Reflecting the lack of consensus on the classification of runners, we will include all runners as defined by study authors. Participation in running will be confirmed by self-report, professional occupation or both. We will exclude track athletes as this population use specialist running footwear (i.e. spikes) not included in this review. Due to factors relating to skeletal immaturity, we will also exclude studies focusing on children from the review (Adirim 2003; Difiori 1999). If studies include a mix of adults and children, then we will make a decision to include the study based on the proportion of children and the balance between groups of children. For example, if the majority in the group are adults then this study may be included (O'Connor 2011). We will also include data from mixed populations (e.g. children and adults) where study authors have provided separate data as subgroups.

Types of interventions

Due to inconsistencies in running shoe definitions (see Description of the intervention), we will include any type of running shoe defined as such by the study author. However, we would expect to find the most common types and characteristics of footwear similar to those presented in Table 1. We will contact study authors if more information on the footwear characteristics is required. We will include studies that compare one or more types of running shoe with a different type of running shoe (e.g. motion control running shoes versus stability running shoes). We will also compare running shoes with shoes defined by study authors as not running shoes. We will exclude non-sporting footwear and footwear that has cleats or studs such as football boots.

1. Running shoe versus shoes not defined as a running shoe by the study author (e.g. motion control (intervention) versus tennis shoe (control)).
2. Running shoe A versus running shoe B. In these comparisons, we will select the control group based on the shoe with the least features that are thought to influence lower limb function. For example, stability (intervention) versus neutral/cushioned (control) and motion control (intervention) versus stability (control). An alternative control group may also be the runner's own running shoe.

3. Footwear recommended and selected on foot posture (intervention) versus footwear not recommended and selected on foot posture (control).

Types of outcome measures

A recent Delphi consensus study defined a running injury as follows: "Running related (training or competition) musculoskeletal pain in the lower limbs that causes a restriction on or stoppage of running (distance, speed, duration, or training) for at least 7 days or 3 consecutive scheduled training sessions, or that requires the runner to consult a physician or other health professional" (Yamato 2015). However, especially given that this definition was unavailable until recently, we will record lower limb injuries as reported and defined by study authors. Likewise, as there is no consistency in the literature regarding reporting of lower-limb running injuries, we will use the study authors' criteria for all outcome measures. We will report outcomes for different time periods: short (e.g. within 12 weeks), intermediate (e.g. up to six months) and long term (e.g. longer than six months). We may review these time points following identification of the studies.

Primary outcomes

1. Number of runners sustaining a lower-limb running injury
2. Number of lower-limb running injuries

Where possible, we will also categorise these primarily by overuse injuries and acute injuries; and secondarily by specific type of injury (e.g. stress fracture, ligament sprain, patello-femoral pain, shin splints) and location of injury (e.g. the hamstrings). We recognise that the focus of studies may be on the prevention of specific injuries, such as stress fractures, and will consider the implications where the reported data are on the target injury rather than overall lower-limb running injuries.

Secondary outcomes

1. Number of runners who failed to return to running or their previous level of running
2. Runner satisfaction with footwear. This may relate to comfort or subjective impression of performance.
3. Adverse events other than injuries. For example, skin complaints, blisters, nail pathology (e.g. onychocryptosis, subungual haematoma, nail loss), infections such as athlete's foot
4. Number of runners requiring hospital admission or surgery, or both, for injury or adverse event

Economic and resource outcomes

We will also record resource use (e.g. cost of footwear; days off work; cost of treatment of injury; number of outpatient visits), other costs and findings of included studies reporting cost-effectiveness analysis.

Search methods for identification of studies

Electronic searches

We will search the Cochrane Bone, Joint and Muscle Trauma Specialised Register, the Cochrane Central Register of Controlled Trials (CENTRAL; current year and issue) in the Cochrane Library, MEDLINE (1946 to present), Embase (1980 to present), AMED (1985 to present), CINAHL Plus (1937 to present) and SPORTDiscus (1985 to present).

In MEDLINE, we will combine subject-specific terms with a modified version of the sensitivity-maximising version of the Cochrane Highly Sensitive Search Strategy for identifying randomised studies (Lefebvre 2011). We will adapt the MEDLINE strategy for searching the other databases listed (Appendix 1).

To find ongoing and recently completed studies, we will search the WHO International Clinical Trials Regsitry Platform search portal (ICTRP), and ClinicalTrials.gov (the US National Institute of Health Clinical Trials search portal).

We will apply no restrictions to language or date of publication.

Searching other resources

We will search the reference lists of all primary studies and review articles, and also relevant manufacturers' websites for study references and information. We will search PubMed for errata or retractions from included studies published in full text. We will also search for conference abstracts from key meetings (e.g. International Conference on Biomechanics in Sport, International Conference on Foot and Ankle Biomechanics). We will search the journal entitled 'Footwear Science' as it is not indexed in the included databases.

Data collection and analysis

Selection of studies

Two review authors (NR and BL) will independently screen titles and abstracts for inclusion of all potential studies identified as a result of the search and code them as 'retrieve' (eligible or potentially eligible/unclear) or 'do not retrieve'. We will retrieve full-text publications and two review authors (NR and BL) will independently screen the full texts to identify studies for inclusion and record reasons for exclusion of ineligible studies. If required, we will attempt to contact study authors to establish study methods and characteristics to help make a decision on eligibility. We will resolve disagreements by consensus or by consultation with a third review author (HG or PD). We will identify and collate multiple reports of the same study, so that each study rather than each report is the unit of interest in the review. We will report the

study selection process using a PRISMA flow diagram and we will tabulate reasons for exclusion (Moher 2009).

Data extraction and management

We will use a data collection form, piloted on at least one study in the review, to extract the following study characteristics and outcome data.

1. Methods: study design, total study duration, number of centres and their locations, study settings, randomisation procedure, allocation, blinding, withdrawals, dates the study was carried out and unit of analysis
2. Participants: number of participants, age (mean, standard deviation and range), sex, type of runner, running experience, running experience classification criteria, injury history, running terrain, running habits, inclusion and exclusion criteria
3. Interventions and comparisons: intervention (type and characteristics of running shoe, prescribed running shoe, brand), comparison (an alternative type of running shoe or another type of shoe or not prescribed running shoe), running distance, running duration, running frequency, use and type of other injury prevention interventions (e.g. stretching, running socks, cool down)
4. Outcomes: primary and secondary outcomes reported, including who by (self-report or other such as a physician), and follow-up time points
5. Notes: funding source and notable conflicts of interest of study authors and any unit of analysis issues.

Two review authors (NR and PG) will independently extract both outcome data and study characteristics of interest that include; participant characteristics, intervention and comparison details, and report them in the characteristics of included studies table. We will record where data are not suitable for inclusion in the analyses or where they are otherwise unusable. We will resolve disagreements by consensus or by consultation with a third review author (RA). One review author (NR) will transfer data into a Review Manager 5 file (RevMan 2014), and a second review author (PD) will validate the information.

Assessment of risk of bias in included studies

Two review authors (NR and RA) will independently assess the risk of bias in each study against the following domains, using criteria in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2017).

1. Random sequence generation (selection bias)
2. Allocation concealment (selection bias)
3. Blinding of participants and personnel (performance bias)
4. Blinding of outcome assessment (detection bias)
5. Incomplete outcome data (attrition bias)
6. Selective outcome reporting (reporting bias)
7. Other bias (e.g. major differences between groups at baseline)

We will resolve disagreements by consensus or through a third review author (PD). We will consider assessing the bias of subjective (e.g. comfort) and objective (e.g. number of injuries) outcome measures separately for performance bias, detection bias and attrition bias. Specifically for studies using cluster randomisation, we will consider the risk of additional bias relating to recruitment, baseline imbalance, loss of clusters, incorrect analysis, and comparability with individually randomised studies, as described in Chapter 16 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

We will grade each domain as high, low, or unclear risk of bias (Higgins 2017), provide a quote from the study, and record our grades in a 'Risk of bias' table. We will summarise the risk of bias for each domain across included studies and report these in a 'Risk of bias summary table' and 'Risk of bias graph'. We will contact study authors for further information about study characteristics where necessary and note correspondence in the 'Risk of bias' table and references.

Measures of treatment effect

We will use risk ratios (RR) with 95% confidence intervals (CIs) for dichotomous data (e.g. injured or not injured).

We will present rate ratios with 95% CIs where the events reported in the study were number of injuries in each group over a particular time period (e.g. a year).

If studies have collected continuous data using the same scale, we will use mean differences (MDs) with 95% CIs. If studies have used different calculations to measure the same outcome, we will use standardised mean differences (SMDs) and 95% CIs. We will use final scores in preference to changes scores.

Unit of analysis issues

While we anticipate that the unit of randomisation will be individual runners in most studies, allocation may be by group or cluster, such as platoons trained by different drill sergeants or physical education instructors, in other studies. Should results reported from cluster-randomised trials be unadjusted, we will use the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2017), to adjust for clustering. In such a case, we will seek an intra-class correlation coefficient (ICC) for a similar study as done in Yeung 2011.

Our primary outcome is the number of runners sustaining one or more lower-limb running injuries. Where studies report injuries rather than number of runners with injuries, we will present these where reported as rate ratios (e.g. number of injuries per person-year) or where rate ratios can be calculated from the raw data. We will use adjusted data as first choice, where available (e.g. rate ratios from Poisson regression models, mean differences from analysis of variance (ANOVAs)).

Where a single study includes multiple study arms, we will only include the relevant arms. We will avoid double-counting where

two comparisons (e.g. sports shoe A versus non-sports shoe and sports shoe B versus non-sports shoe) are combined in the same meta-analysis. Thus we will combine the active arms or, if each active arm is presented separately, halve the control group to avoid double-counting.

For cross-over trials, we will use only data from the first, pre-cross-over phase to minimise potential bias from carry-over effects (e.g. an injury).

Dealing with missing data

We will contact study investigators to verify key study characteristics and to obtain missing numerical outcome data (e.g. instances where only the abstract is available). When this is not possible and we consider missing data to introduce serious bias, we will explore the impact of including such studies in the results by performing a sensitivity analysis. We will also consider if the study data were analysed on an intention-to-treat basis whenever possible. Where data are missing in the study text, details available in graphical format may be utilised, but only if this is a reliable representation of the study findings. If a study does not report SDs for continuous outcomes, we will calculate these from standard errors, CIs, or exact probability (P) values where possible. However, we will not impute missing SDs.

Assessment of heterogeneity

We will assess clinical heterogeneity of study populations, interventions and outcomes qualitatively and by visually inspecting forest plots (Deeks 2017). We will use both the I^2 (Higgins 2003), and Chi^2 statistics to measure statistical heterogeneity among studies in each analysis (Deeks 2017). We will interpret I^2 statistic values using recommendations from Deeks 2017; 0% to 40% might not be important; 30% to 60% may represent moderate heterogeneity; 50% to 90% may represent substantial heterogeneity; and 75% to 100% may represent very substantial heterogeneity.

Assessment of reporting biases

We will attempt to reduce publication bias in our search methods by including published and unpublished studies without language or date restrictions. We will also check reported study data against any available published protocols. Furthermore, we will dedicate one section of the 'Risk of bias' assessment to selective outcome reporting. We will also search for unpublished studies, including documentation on shoe manufacturers' websites, and contact shoe manufacturers to reduce publication bias. If we use meta-analysis to pool more than 10 studies, we will create and examine a funnel plot to explore the potential effects of small studies and publication biases (Sterne 2017).

Data synthesis

When considered appropriate, we will pool the results of comparable studies using both fixed-effect and random-effects models. The choice of the model to report will be guided by careful consideration of the extent of heterogeneity and whether it can be explained, in addition to other factors such as the number and size of included studies. We will use 95% CIs throughout. We will consider not pooling data where there is substantial heterogeneity ($I^2 \geq 75\%$) that cannot be explained by the diversity of methodological or clinical features among studies. Where pooling data is inappropriate, we will still present study data in the analyses or tables for illustrative purposes and will report these in the text.

When considered appropriate, we will pool data using the generic inverse variance method in Review Manager 5 (RevMan 2014). This method enables pooling of the adjusted and unadjusted treatment effect estimates (e.g. rate ratios) reported in the individual studies or that can be calculated from data presented in the published article.

GRADE assessment and 'Summary of Findings' tables

We will create a 'Summary of findings' table using the following outcomes: number of runners sustaining a lower-limb running injury; number of lower-limb running injuries; number of overuse injuries; number of acute injuries; number of runners who failed to return to running or their previous level of running; runner satisfaction with footwear; and adverse effects. We will create a 'Summary of findings' table for each of our main comparisons.

We will use the five GRADE considerations for downgrading the certainty of evidence (study limitations, inconsistency of effect, imprecision, indirectness and publication bias) to assess overall confidence in the strength of evidence that contributes to these outcomes. We will use methods and recommendations described in Chapter 11 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2017), using GRADEproGDT software (GRADEpro GDT). We will use record justification for our assessment of the certainty of evidence for individual outcomes.

Subgroup analysis and investigation of heterogeneity

1. Type of runner (e.g. novice, recreational, elite/professional).

There is conflicting evidence that the type of runner is associated with higher injury rates (Van Gent 2007). Although there is no consensus definition for this classification and we will use descriptions provided in study reports, provisional definitions of these three categories are:

i) a novice runner may have no experience or less than two years' regular running experience, may have run for less than a total of 10 km in the previous 12 months (Baltich 2017; Buist 2008; Buist 2010; Ramskov 2015);

ii) a recreational runner may have run at least once a week for 12 months, at least 10 km per week annually or

running on average 10- to 11-minute miles (Malisoux 2015; Van Mechelen 1993; Wen 1998);

iii) professional or elite runners are typically full-time athletes and include military recruits who run during basic training (Kornaat 2014; Yeung 2011).

2. Footwear type definition criteria (e.g. motion control, stability, cushioned/neutral) or not defined (e.g. simply referred to as a running shoe) when compared with non-running shoes

3. Footwear assigned on foot posture (e.g. excessive pronation, neutral, supination). Traditional guidance from some health professionals recommend runners seek expert advice to select the most appropriate shoe for their foot posture (Asplund 2005). However, Richards 2009 stated that there may be no evidence to support the prescription of running footwear on foot posture.

4. Running distance (e.g. training distance per week). A previous systematic review reports that some lower limb running injuries may be related to greater weekly training distances (Van Gent 2007). However, evidence also suggests that running distance can be a protective factor (Van Gent 2007), with suggestive thresholds of 30 km per week for 21 km runners and 45 km per week for 42 km runners (Besomi 2019).

5. Running terrain (e.g. treadmill, road)

6. Injury report and confirmation method (e.g. by a physician or healthcare professional or self-reported by the runner)

7. Sex: female runners may be more at risk of overall lower limb running injuries, but these differences may not be apparent when considering specific types of injury, such as hamstring or calf injuries (Van Gent 2007).

8. Age: Van Gent 2007 reported conflicted evidence to suggest that older age is associated with an increase in running injuries. However, we will use a provisional threshold of 40 years of age (Satterthwaite 1999).

9. Studies completed pre- and post-Yamato 2015 injury definition

We will conduct subgroup analyses for outcomes with a sufficient number of studies. We will use Review Manager's test for subgroup differences alongside visual inspection of confidence intervals to complete subgroup analysis (RevMan 2014).

Sensitivity analysis

We will undertake sensitivity analyses to assess whether the results of the review are robust to the decisions made during the review process. We plan to examine the effects on the review findings of the following.

1. Excluding studies at high or unclear risk of bias, primarily selection bias, detection bias and attrition bias

2. Excluding studies published in conference proceedings or abstracts only

3. Excluding studies with data that have not been systematically collected and have been poorly reported

4. Excluding studies where there are potential or known unit of analysis issues

5. Excluding mixed population studies

6. Excluding studies that do not describe the characteristics of the footwear using recognised criteria (Table 1; Ramsey 2019)

7. Excluding studies that report on specific types of injury (e.g. stress fractures) instead of overall running injuries

8. Adjusting for missing data

9. Using different ICCs for adjusting the results of cluster-RCTs

10. Using fixed-effect versus random-effects models for pooling data

We will report any sensitivity analysis in the text and in summary tables, where helpful.

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* *Indicates the major publication for the study*

ADDITIONAL TABLES

Table 1. Common design features of motion control, stability, neutral/cushioned and minimalistic running shoes

Design feature	Motion control	Stability	Neutral/cushioned	Minimalistic
Flexibility	Rigid	Rigid rearfoot Flexible forefoot	Flexible	Flexible
Mid-sole	Firm Multi-density (firmer on medial aspect)	Intermediate Multi-density (firmer on medial aspect)	Soft Multi-density (firmer on medial aspect)	Soft
Heel counter	Rigid Reinforced	Rigid	Rigid	No
Medial posting	Yes	Yes	Varies	No
Torsion control system (midfoot trussic)	Yes (reinforced)	Yes	Varies	No
Heel height (mm)	22-30	22-30	22-30	2-8
Forefoot height (mm)	12-24	12-24	12-20	2-8
Heel-toe drop (mm)	10-12	5-12	8-10	0-6
Weight (grams)	290-416	290-330	200-310	120-212

These values are not exhaustive and differences between manufacturers and models of shoe are common.

APPENDICES

Appendix 1. Search strategies

MEDLINE (Ovid Interface)

1 exp Running/ or Sports/ or "Track and Field"/ or Athletes/ or Athletic Injuries/
2 Military Personnel/ or Naval Medicine/ or Military Medicine/
3 (runn* or jog* or sprint* or athlet* or overuse*).tw.
4 1 or 2 or 3
5 shoes/
6 (footwear or shoe* or footgear or shod).tw.
7 5 and 6
8 randomized controlled trial.pt.
9 controlled clinical trial.pt.
10 randomized.ab.
11 placebo.ab.
12 randomly.ab.
13 trial.ab.
14 groups.ab.
15 8 or 9 or 10 or 11 or 12 or 13 or 14
16 exp animals/ not humans.sh.
17 15 not 16
18 4 and 7 and 17

CONTRIBUTIONS OF AUTHORS

NR: wrote the protocol: all sections, and acts as guarantor

HG: wrote the protocol: background

RA: wrote the protocol: methods

PG: wrote the protocol: methods

TP: wrote the protocol: background

IG: wrote the protocol; background

SS: wrote the protocol: all sections

PD: wrote the protocol: all sections

BL: wrote the protocol: background

All authors contributed to, and approved, the final version of the protocol.

Contributions of editorial base

Helen Handoll: edited the protocol; advised on methodology and protocol content; and approved the final version for publication.
Joanne Elliott: provided editorial support.
Maria Clarke: designed the search strategy and edited the search methods section.

DECLARATIONS OF INTEREST

NR: none

HG: none

RA: none

PG: none

TP: Trevor Prior is acting as an advisor to the Saloman Company Think Tank.

IG: none

SS: none

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BL: Dr Ben Langley has previously undertaken research funded by Anima Sana in Corpore Sano (ASICS). However, the nature of Dr Langley's previous work and the proposed work would not be eligible for inclusion within the review and focuses more on how running shoe modification or types of running shoes influence potential markers of injury risk or performance rather than injury occurrence.

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